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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,441	03/01/2006	Soren Persson	SSI7USA	7400

270 7590 06/19/2008

HOWSON AND HOWSON
SUITE 210
501 OFFICE CENTER DRIVE
FT WASHINGTON, PA 19034

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
06/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,441	PERSSON ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 39-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

> Group I, claim(s) 1 and 39-60 are drawn to a screening method for simultaneous detection of diarrheagenic *Shigella* species and *E. coli* (DEC) including A/EEC & EPEC, ETEC, VTEC, EIEC and strains with the *ehxA* gene wherein the method comprises A SINGLE primer selected from Table 3 and A SINGLE probe from Table 7.

2. The inventions listed as Groups I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of claim 1 is a screening method for simultaneous detection of diarrheagenic *Shigella* species and *E. coli* (DEC) including A/EEC & EPEC, ETEC, VTEC, EIEC and strains with the *ehxA* gene wherein the method comprises A SINGLE primer selected from Table 3 and A SINGLE probe from Table 7.

The art of Pielken et al. (WO 98/48046) teach the detection of pathogenic *E.coli* providing specific optimized primers and labeled oligonucleotide probes useful for the amplification of sequences encoding virulence factors/toxins characteristics of pathogenic *E.coli*. Therefore, Unity of Invention is not fulfilled because there is not a technical feature that is "special", in that the technical feature does not define a

contribution over the art. As such, the screening method for simultaneous detection of diarrheagenic *Shigella* species and *E. coli* (DEC) including A/EEC & EPEC, ETEC, VTEC, EIEC and strains with the *ehxA* gene wherein the method comprises A SINGLE primer selected from Table 3 and A SINGLE probe from Table 7set forth in Inventions of Group I do not require the use of the technical feature; since they define separate technical features as set fort supra,

The inventions listed as Groups I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The groups are drawn to a plurality of disclosed patentably distinct nucleic acid sequences comprising materially different nucleic acids as evidence by separate primer and probe sequences provided within the specification at Tables 3 and 7. The separate nucleic acid sequences bear distinct structural or biochemical properties. For instance, the first sequence within Table 3 s associated with heat labile entero-toxin I while the last sequence is associated with 16 RDNA. Therefore, each disclosed patentably distinct sequence is considered a separate invention. Each invention performs its function using a structurally and functionally divergent material. The groups are directed to different molecules which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct nucleic acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Therefore, each method is unrelated. Therefore,

the special technical feature is comprised within the each group's sequences; therefore the groups lack the same or corresponding technical feature. Finally, groups are unrelated and do not share a special technical feature because each method has a separate and distinct purpose with separate and distinct final outcomes and comprises different virulence factors. The Inventions lack unity of invention because they do not form a single general concept.

3. Applicant is required, in reply to this action, to elect a SINGLE SEQUENCE from Table 3 and A SINGLE SEQUENCE from Table 7 to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected SEQUENCE, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). If applicant elect Invention I, they should also elect a SINGLE SEQUENCE from Table 3 and Table 7 as set forth supra.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825.

A) The sequence listings supplied January 12, 2006 does not correlate with the sequences set forth in Tables 3 and 7. Therefore Applicants is requested to confirm that the sequences described within the specification match the sequences shown in the Tables. Because Tables 3 and 7 refers to sequences without sequence identifying numbers being described within the figure itself or within the specification; appropriate correction is requested.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645